

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

compare the alteration of vitamin D deficiency in patients candidate for bariatric surgery with vitamin D deficiency in various methods oral ,injection and mix of two methods in azahra hospital in esfahan.

Protocol summary

Study aim

1. A survey and compare to average of vitamin D level in patients candidate for bariatric surgery with vitamin D deficiency before and after receive vitamin D supplement into oral and injection and mix of two methods. 2. Determine amount of cooperation in patients candidate for bariatric surgery with vitamin D deficiency before surgery into oral and injection and mix of two methods.

Design

A concealed with no control groups , based on society and pragmatic, parallel groups, one side blinded, randomized.

Settings and conduct

This study done in alzahra hospital in esfahan on patients candidate for Bariatric surgery who have vitamin D deficiency. Give them defined amount of vitamin D supplement and check the vitamin D , level again and record. Study was one side blinded.

Participants/Inclusion and exclusion criteria

Entrance terms patients candidate for Bariatric surgery with vitamin D deficiency and interest to cooperate in this project. Nonentrance terms ; patients who didnot candidate for bariatric surgery or candidate for bariatric surgery but have normal level of vitamin D and indisposition to cooperate in project

Intervention groups

A study to alteration of vitamin D level after advising vitamin supplement in to oral in group 1 A study to alteration of vitamin D level after advising vitamin supplement in to Injection in group 2 A study to alteration of vitamin D level after advising vitamin supplement in to mix of two methods in group 3

Main outcome variables

Vitamin D level in obese patient

General information

Reason for update

Acronym

EVS

IRCT registration information

IRCT registration number: **IRCT20180312039067N1**

Registration date: **2018-06-29, 1397/04/08**

Registration timing: **retrospective**

Last update: **2018-06-29, 1397/04/08**

Update count: **0**

Registration date

2018-06-29, 1397/04/08

Registrant information

Name

masoud sayadi shahraki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3667 1832

Email address

sayadi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

2016-03-20, 1395/01/01

Actual recruitment end date

2017-07-23, 1396/05/01

Trial completion date

empty

Scientific title

compare the alteration of vitamin D deficiency in patients candidate for bariatric surgery with vitamin D deficiency in varous methods oral ,injection and mix of two methods in azahra hospital in esfahan.

Public title

A survey to compare the alteration of vitamin D deficiency in patients candidate for bariatric surgery with vitamin D deficiency in varous methods oral, injection and mix of two methods in azahra hospital in esfahan.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patiens candidate bariatrics surgery Vitamin D deficiency

Exclusion criteria:

No candidation for bariatric surgery Normal level of vitamin D Dissatisfaction

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **99**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomized-individual-random Patients with qualify to research get one of the methods of supplement randomized and random.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan University of Medical Sciences

Street address

hezar jarib ave, medical faculty ,ethics committee

City

Esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2017-01-21, 1395/11/02

Ethics committee reference number

. IR.MUI.REC.1395.3.765

Health conditions studied

1

Description of health condition studied

Endocrine, nutritional and metabolic diseases

ICD-10 code

E55

ICD-10 code description

Vitamin D deficiency

Primary outcomes

1

Description

vitamin D level in obes patients

Timepoint

To measure of vitamin D level before and after supplement reciept (6 weeks later)

Method of measurement

Vitamin D level in blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: : Give to group1 ,six pearl of vit D 50000 IU week one for six weeks

Category

Treatment - Drugs

2

Description

Intervention group: give to group2 , one vit D ampoul 300000 IU

Category

Treatment - Drugs

3

Description

Intervention group: give to group3 , 3 vit D pearl 50000IU week one for three weeks and half of the vit D ampoule 300000 IU for the next three weeks

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Masoud sayadi

Street address

Alzahra hospital , soffe Blvd

City

Esfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

sayadi@med.mui.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahboobe shojaei

Street address

Isfahan university of medical sciences ,isfahan ,iran

City

Esfahan

Province

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Email

sayadi@med.mui.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin
Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Masoud Sayadi

Position

Consultant

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Number5 , Mahan Convened, West aban alley ,Kharazmi avenue, Sepahanshahr

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available